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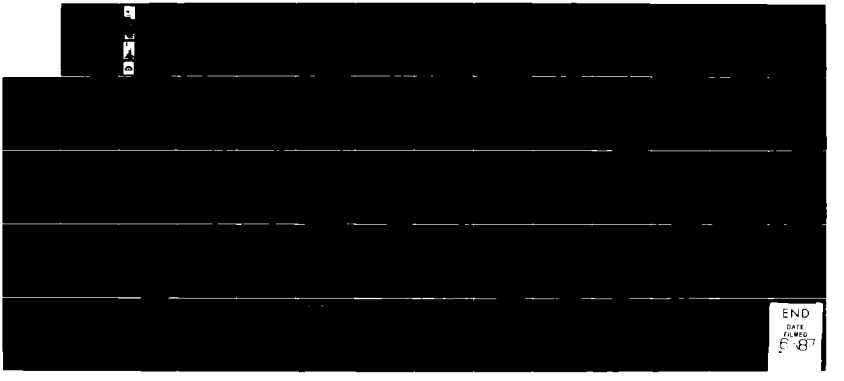

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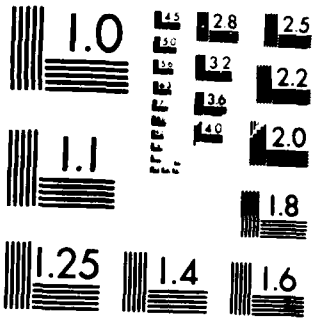

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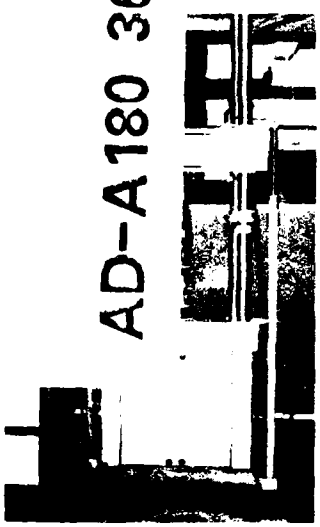

STRUCTURES LABORATORY

MANUAL FOR THE RESEARCH QUALITY MANAGEMENT SYSTEM, STRUCTURES LABORATORY, CONCRETE TECHNOLOGY DIVISION

by

Lillian D. Wakeley

Structures Laboratory

DEPARTMENT OF THE ARMY
Waterways Experiment Station, Corps of Engineers
PO Box 631, Vicksburg, Mississippi 39180-0631

March 1987
Final Report

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A Research Quality Management System has been established to direct quality practices in research and testing in the Concrete Technology Division (CTD) of the Structures Laboratory at the US Army Engineer Waterways Experiment Station. This system covers all aspects of research and test plans, standard and nonstandard test methods, data analysis, and documentation for projects undertaken within or contracted from the CTD. It describes implementation of the system among CTD staff, emphasizing calibration and verification of test equipment, training in quality assurance and standard practices, and documentation of these. It includes descriptions of systems for numbering research and test materials and specimens, and guidelines for justified departures from the American Society for Testing and Materials (ASTM) or other standard practices. The use of such communication tools as Research and Technical Project Plans, nonconformance reports, and other standard forms of documentation are described. A glossary and examples of standard forms appear in Appendices.

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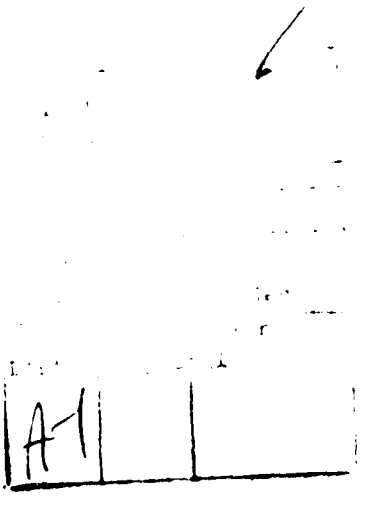
PREFACE

This Manual for the Research Quality Management System (RQMS) was prepared in 1986 in response to a need to update and replace the Structures Laboratory Quality Assurance (QA) Manual, in order to better meet the requirements of sponsors; as well as to provide the Concrete Technology Division (CTD) of the Structures Laboratory (SL), US Army Engineer Waterways Experiment Station (USAEWES), with a more workable system. The RQMS will be used by all CTD employees. It applies to all projects, regardless of sponsor or scope, that are conducted within the CTD.

The RQMS was prepared by members of the staff of the SL under the direction of Messrs. Bryant Mather, Chief, SL, and John M. Scanlon, Jr., Chief, CTD. Dr. Lillian D. Wakeley was the principal author, with assistance from Mrs. Joyce C. Ahlvin, and Messrs. Richard L. Stowe, Joe G. Tom, Edward F. O'Neil III, G. Sam Wong, Kenneth L. Saucier, and Bryant Mather.

COL Dwayne G. Lee, CE, is the Commander and Director of WES. The Technical Director is Dr. Robert W. Whalin.



CONTENTS

MANUAL FOR THE RESEARCH QUALITY MANAGEMENT SYSTEM, STRUCTURES LABORATORY CONCRETE TECHNOLOGY DIVISION

I. Introduction to the System

I.A. Management Statement and Purpose

This document is the plan for the Research Quality Management (RQM) System implemented in the Concrete Technology Division (CTD), Structures Laboratory (SL), Waterways Experiment Station (WES), during the fourth quarter of fiscal year 1986 (FY 86). The Quality Assurance (QA) practices described here apply to all research and testing programs for which the CTD has responsibility. The term "RQM System" applies to all system elements; "RQM Manual" refers specifically to this document.

A major purpose of the RQM System is to assure that the CTD staff and others supplying support to CTD projects continue to perform quality work. Another purpose is to assure that the work is documented according to a consistent format, which permits ready retrieval of the information at any time. The System should ensure that procedures are selected to yield the required results; and that equipment and personnel are performing at the level of precision and bias required by the intended use of the data. The RQM System provides documented records to assure sponsors and potential sponsors that quality practices are routine in the CTD. It also streamlines the processes of technology transfer and preparation of reports, which are the essential and tangible products of research and testing in the CTD.

The RQMS is comprehensive in its coverage of the quality assurance procedures to be followed and the various forms to be used. When necessary, revisions to the procedures and forms will be prepared. When a revision is distributed, each holder of a copy of the RQMS shall replace the page(s) in his(her) copy promptly to assure continuous, uniform, quality assurance activities.

Implementation is the key to this RQM System. Implementation requires that each member of the staff of the CTD understands the goals and mechanics of the System, and that each participates continuously in its operation, maintenance, review, or updating as needed. This Manual describes the procedural controls necessary for assuring and controlling quality, through such elements as integrity of data through its generation, validation, preservation, and retrieval.

I.B. Source Documents

Elements of the RQM System are designed to fulfill the requirements of QA identified by CTD management and QA advisors.

Source documents consulted in devising this System and its Manual include: EP401423 of Sandia National Laboratories; ANSI/ASME NQA-1-1983, "QA Program Requirements for Nuclear Facilities," with requirements modified or interpreted such that they apply to all CTD projects; the previous SL QA Manual, Revision D; portions of the QA Plan of the Salt Repository Project Office, Revision 0 as applicable to CTD projects; and the QA Program of the Materials Research Laboratory of the Pennsylvania State University (PSU), QAP/MRL/ONWI-1980, Revision 1.

I.C. Other Procedural Documents in this System

In addition to this Manual, other documents that are important elements of the System include, but are not limited to:

1. Annual Book of ASTM Standards, applicable volumes

2. U.S. Army Corps of Engineers Handbook for Concrete and Cement (updated quarterly)

3. American Concrete Institute Manual of Concrete Practice, Parts 1 through 5 (revised annually)

4. Documentation for the CTD Materials Management System

5. Computer Program Abstracts (WES Form 2370) and software documentation

These references are used routinely in the CTD. Appendix D lists the categories of records and documents maintained under this System. A glossary of important terms is included as Appendix A.

I.D. The Handbook for Concrete and Cement

I.D.1. Issuing the Handbook

A copy of the Handbook for Concrete and Cement is provided to each technical staff member of the WES shortly after the staff person has joined CTD. The copy should be ordered from Technical Reports Distribution Section (WESIM-TS-T) by the supervisor and the person to whom it is issued should have his or her name added to the list maintained by WESIM-TS-T to whom copies of Quarterly Supplements are issued by WESIM-TS-T. (The internal SL distribution previously made by WESSV-Z has been discontinued). When a person to whom a Handbook has been issued leaves the CTD he/she may, if desired, take the

Handbook along. If the person remains in the service of the federal government supplements will be furnished as issued if WESIM-TS-T has the correct address; if no longer in federal service, the person can order supplements sent to his/her address for $8.00 per year. Any Handbook abandoned by a former CTD staff member should be returned to WESIM-TS-T for salvage.

I.D.2. Maintaining and Using the Handbook

Each person to whom a copy of the Handbook is issued is responsible for keeping his or her copy updated, by adding the quarterly supplements and discarding the outdated sections thus replaced. Each supervisor will issue copies of relevant sections of the Handbook to any employees who are not on the regular circulation list but who are required to participate in work involving procedures from the Handbook. All persons are responsible for becoming familiar with and following Handbook procedures. Any person who has not been issued a Handbook and feels a need for one should request this of his/her supervisor.

II. Organization and Responsibilities

II.A. Concrete Technology Division

The CTD is one of four divisions of the Structures Laboratory (SL), with primary responsibility for: 1) conducting research to increase the quality and reduce the cost of concrete, 2) providing investigational services for evaluating and rehabilitation of concrete structures, and 3) conducting research on special grouts, mortars, and concretes as necessary for use in special water resource projects and for military applications. Its staff and facilities are well suited to interdisciplinary studies in engineering and the physical sciences.

Members of the professional staff of the CTD have primary responsibility for research under this System, which is accomplished with assistance from technical staff, other WES elements, and qualified individuals and groups from outside WES operating by Interagency Agreement or under contract. Research within the CTD is under the direction of Mr. Bryant Mather, Chief, SL, Mr. James Ballard, Assistant Chief, SL, and Mr. John M. Scanlon, Chief, CTD.

Table II.0 lists the lines of authority among CTD employees. Individual Project Managers (or Principal Investigators (PI)) will be identified for each project in its initial Project Plan (Section III.A).

II.B. CTD Quality Assurance Manager

The QA manager in cooperation with the Chief, CTD, is responsible for:

1. Assuring that the RQM System is established and effectively and continuously implemented.

Table II.0

CONCRETE TECHNOLOGY DIVISION

Scanlon, John M., Jr.	Chief
Supv Civil Engineer	GM-15
Ext 3277	
1 QA Manager	GS-11
1 Secretary (Steno)	GS-05
1 Clerk Typist (Temp)	GS-03

CONCRETE AND EVALUATION GROUP

Saucier, Kenneth L.	Chief
Supv Civil Engineer	GM-14
Ext 3251	

EVALUATION AND MONITORING UNIT

Thornton, Henry T., Jr.	Chief
Supv Res Physicist	GM-13
Ext 3797	
2 Res Physicist (Mech)	GS-13
1 Res Civil Engineer	GS-13
2 Res Physicist (Mech)	GS-12
1 Res Civil Engineer	GS-12
1 Mechanical Engineer	GS-11
1 Civil Engineer	GS-09
1 Matls Engrg Tech	GS-09
1 Matls Engrg Tech	GS-07
2 Matls Engrg Tech	GS-06
1 Matls Engrg Tech	GS-05
1 Stu Trainee (Engrg)	GS-05
1 Matls Engrg Tech (Temp)	GS-04

CONCRETE AND GROUT UNIT

Ragan, Steven A.	Chief
Supv Civil Engineer	GM-13
Ext 3253	
1 Geologist	GM-13
2 Geologist	GS-12
1 Civil Engineer	GS-12
3 Civil Engineer	GS-11
3 Matls Engrg Tech	GS-09
1 Matls Engrg Tech	GS-08
2 Matls Engrg Tech	GS-07
1 Geologist (Temp)	GS-05
3 Matls Engrg Tech	GS-05

RESEARCH GROUP

2 Res Civil Engineer	GS-14
1 Geologist	GS-14
1 Res Civil Engineer	GS-13

REMR RESEARCH

McCleese, William F.	Chief
Civil Engineer	GM-14
Ext 2512	
1 Deputy Program Mgr	CPT
1 Tech. Transfer Spec.	GS-09
1 Secretary	GS-04
1 Stu Trainee (Comp Sci)	GS-02

MATERIALS AND CONCRETE ANALYSIS GROUP

Stowe, Richard L.	Chief
Supv Geologist	GM-14
Ext 3254	
1 Geologist	GS-13
1 Civil Engineer	GS-13
1 Civil Engineer	GS-12
1 Matls Res Engineer	GS-12
1 Matls Engrg Tech	GS-09
1 Clerk-Typist (Temp)	GS-03

CEMENT AND POZZOLAN UNIT

Poole, Toy S.	Chief
Supv Chemist	GS-12
Ext 3261	
1 Chemist	GS-11
1 Physical Sci Tech	GS-07
1 Physical Sci Tech	GS-06
1 Physical Sci Tech	GS-05
1 Clerk-Typist	GS-04

CHEMISTRY UNIT

1 Research Chemist	GS-13
2 Chemist	GS-11
1 Physical Sci Tech	GS-04

PETROGRAPHY UNIT

1 Geologist	GS-13
2 Geologist	GS-11
1 Physical Sci Tech	GS-07

2. Establishing independent controls to verify conformance to necessary quality requirements.

3. Initiating, recommending, concurring in, or providing solutions to quality problems through designated channels.

4. Representing the programs in matters of QA and control.

Analytical and support services provided by other elements of WES or by outside sources, as well as material suppliers to CTD programs, will be subject to CTD RQM System requirements as applicable.

The QA manager will have the authority and organizational freedom to perform the QA functions effectively and without reservation. The QA manager will have the authority to control further processing, experimentation, testing, or shipment by suppliers until proper dispositioning of nonconforming items has occurred.

The QA manager will have direct access to the Chief, CTD, who will ensure accomplishment of quality-affecting activities. Responsibilities 1 through 4 as well as the required organizational freedom and authority is implied to all personnel performing QA functions.

The QA manager will work with the Chief, CTD, and Group Chiefs, or other appropriate individuals designated by the Chief, CTD, to revise the RQMS annually or at other intervals as needed.

II.C. Acting QA Manager

In the absence of the QA manager, the Chief, CTD, will appoint an Acting QA manager to perform these functions. Rules governing such absences are given in Station Regulation 1-1-9, "Assumption of Duties During Absence of Key Personnel."

III. Design and Review of Research and Testing Project Plans

III.A. Project Plans

III.A.1. Research Project Plans (RPP)

The PI for a project will prepare a Project Plan for that project. An RPP (formerly Memorandum for All Concerned (MFAC)) is required for each research project. Research projects are those which comprise experimentation or investigation to answer specific questions, rather than simply to determine if a material or process meets a standard or specification. Usually, the course of events in a research project is documented after the fact or in successively dependent steps (what you do next depends on what just happened.

Standard procedures will be specified and followed in some of the steps, but other steps will require documented departures from a prescribed standard, because research is developmental by nature. The amount of detail about procedures will vary among RPP's, because some projects will require developmental work almost exclusively. Detail will be added in successive memos or other documents (see Section IV.A and B).

The sponsor may require the opportunity to review and approve a project plan before it is issued, by agreement at the outset of a project.

Table III.0 lists the information that the PI must provide for an RPP which will be prepared according to AR format. The plans are numbered consecutively in the office of the Chief, CTD, by FY and number (example: 87-13), and require his or her signature.

III.A.2. Technical Project Plans (TPP)

A TPP is required for tests, where the data generated by following standard procedures are themselves the objective, and for other technical activities involving neither research nor testing, such as schools and short courses offered by the CTD. Although it is advisable to have TPP's for all technical projects, they are required only for those projects which will involve people in more than one Unit. A Technical Project Plan will be prepared by the CTD staff member responsible for the testing, or other activity, or by another individual designated by the appropriate Group or Unit Chief. They are numbered in the office of the Chief, CTD, (FY suffix M for M&CAG, C for C&EG), consecutively through the fiscal year (example: 87C-1; 87M-14). Table III.1 lists the requirements of a TPP.

For very small projects, the Group Chief may choose simpler documentation, such as a Disposition Form (DA Form 2496), or Conversation Record (Form 271), in place of the usual TPP.

III.B. Design Review and Approval

The PI responsible for a Research Project will route a draft of each plan (clearly marked "DRAFT") through the appropriate Group Chief, to the Chief, CTD, in whose office the Plans will be consecutively numbered throughout the fiscal year. The Chief, CTD, is responsible for reviewing the plan or assuring review by another qualified individual, to assure appropriateness and technical merits of the plan. The assigned reviewer(s) will be (an) individual(s) not directly involved in the research. They will sign the draft Plan (Table III.0, item 9), either approving or disapproving. Disapproval requires written comments, routed to the Chief, CTD, so that the Plan can be revised as needed.

Table III.0

CONCRETE TECHNOLOGY DIVISION
RESEARCH PROJECT PLAN

Research Project Plan and No.: Job Number:

Subject of Project:

1. Principal Investigator

   a. Name

   b. *Group and Unit*

   c. Ext.

2. Sponsor and Authority. Source of funding, identifying numbers of documents from sponsor or other documents requesting that the work be performed.

3. Objectives. State the specific reasons this project is being undertaken. This should explain what the sponsor (and the Principal Investigator (PI)) expect to get out of it, and why it is being done.

4. Background. Relate the work to the big picture, and to other recent projects on a similar theme. This will help people who are new to projects for this sponsor understand what they are supposed to be doing. It also is necessary for peer review.

5. Task Definitions. Describe each task individually. Give whatever detail you can, at the outset of the project, about order of events and methods to be used. Additional details can be provided later, in amendments (if work is added, or subtracted, or if there are changes in time, funding, or reporting requirements); or in Disposition Forms, internal memorandums, or Memorandums for Record. Refer to this Research Project Plan (RPP) by number in all subsequent documents.

6. People and Responsibilities. List of the people who will be required to participate responsibly in the project, and generally what they will be doing. Refer to standard practices if possible. All of these people get a copy of the RPP. This list must be cleared by the individual and his/her supervisor prior to being included in the draft RPP.

7. Schedule and Funding: State the time period in which the project will be completed. Give key dates for each Task if applicable. Give the total amount of funding for each task.

Table III.0 (Continued)

Table III.0 (Concluded)

8. Records and Reports. State the types of records each staff member will keep. This includes notebooks, data sheets, standard forms, etc. List dates reports are due and who will write them. This includes reports from the staff to the PI or from the PI or other professional to the sponsor. State who will contribute to each, and what they are required to report. State the types of reports required by the sponsor: letter, monthly, quarterly, final, Technical Reports, etc.

9. Technical Review. All plans are reviewed before being issued in final form by the Chief, CTD, or other qualified individual whom he/she designates. Disapproval requires written comments, which are provided to the Chief, CTD, and the author of the RPP.

Signature Block

Table III.1

CONCRETE TECHNOLOGY DIVISION
TECHNICAL PROJECT PLAN

Technical Project Plan and No.: Job Number:

Subject of Project:

1. Principal Investigator

   a. Name

   b. Group and Unit

   c. Ext

2. Sponsor and Authority. Source of funding, identifying numbers of documents from sponsor or other documents requesting that the work be performed.

3. Materials to be Tested or Technical Subject. List the materials by descriptive term and by the Concrete Technology Division (CTD) Materials Identification ("Check-in") number. If other technical subject, give details.

4. Tests or Other Activities to be Performed. List the tests that will be done on each material by descriptive name, and by CRD-C or ASTM number, or both; or refer to other CTD test methods. If other activities are to be performed, describe those activities.

5. People and Responsibilities. List everyone who will participate responsibly in the Technical Project, and what tests each will perform.

6. Completion Date. State the time period in which the project will be completed. Give key dates for each test if applicable.

7. Records and Reports. State the types of records each staff member will keep. This includes notebooks, data sheets, standard forms, etc. List dates reports are due and who will prepare them. State who will contribute to reports, and what they will contribute (data, graphs, tables, etc.). State the types of reports requested by the sponsor: letter, monthly, quarterly, final, etc.

Signature Block

Copies of each RPP after it has been reviewed, approved, and signed by the Chief, CTD, (in its final form) are kept by the PI, in the project files if required by a sponsor, and in the office of the Chief, CTD. Also, copies are provided to each individual who will participate in or be responsible for a portion of the project.

TPP's are routed for review, comment, and approval, through the Group Chief. They will then be routed to the Chief, CTD, for purposes of signing and making the Chief, CTD, aware of the volume of routine testing in CTD. Copies are filed by the person responsible, and in the office of the Chief, CTD. Also, copies are provided to all persons who will be performing tests.

III.C. Providing Copies of Project Plans

Copies of all Research or Technical Project Plans also are provided to: Chief, SL, Group and Unit Chiefs, CTD staff members involved in the project, and to all other support or contract individuals or organizations participating in the project. The PI also provides a copy to the sponsoring agency. Review of draft plans may be required by the sponsor before the Plan is issued.

IV. Control of Experiments and Tests

IV.A. Amendments to RPP

Major changes in a RPP, as determined by agreement between PI and sponsor, must be documented in amendments to the original Plan. Amendments have the same format, as described in Table III.0. They carry the number of the original RPP, with consecutive letter suffixes (first issued amendment to RPP 87-6 is 87-6A). They must be numbered in the Division Office, and routed to, reviewed, and signed by the Chief, CTD; or reviewed by another qualified individual assigned by the Chief, CTD.

Changes requiring amendments include:

1. Tasks being added to or deleted from the original plan.

2. Substantial changes in task descriptions.

3. Changes in time, funding, or reporting schedules.

The PI may choose to issue an amendment to add more detail to task descriptions, if this could not be provided initially. Documents described in IV.B also may be used for this purpose, but must refer specifically to the initial RPP, by number.

IV.B. Other Documents Controlling Experiments or Tests

Minor changes in a Project Plan, and other project-related information, can be communicated by any participant on the project by less formal means. These include WES Office Memorandum (WES Form 1741); Disposition Form (DA Form 2496); Conversation Record (Optional Form 271); and Memorandum for Record. Appendix B includes copies of the three forms. Instructions for their use are in AR 340-15.

Project activities and changes to be documented by these means include:

1. Calling or summarizing meetings;

2. Written discussions of results or problems with potential impact on the research;

3. More specifics of a task spelled our for one or more of the project participants;

4. Changes in staff members participating in the project, or assignment changes among participants;

5. Alterations in developmental or experimental procedures (changing tactics while still aiming toward the original goal).

6. Conversations between project participants and the sponsor's representatives.

Information about changes in other aspects of TPP generally do not require formal amendments, but can be adequately documented by one or more of these Memorandums or Forms.

IV.C. Responsibilities in Following a Project Plan

The PI is responsible for preparing and following the Project Plan and any amendments to it or other statements of change. He or she also is responsible for accomplishing the tasks described in those documents; and for providing other staff members with information and instruction adequate to complete the described tasks, according to the specifications and practices of the RQM System. To accomplish this, the PI will conduct internal project meetings at appropriate intervals. Part of the agenda of these meetings will be devoted to QA matters and development of operating procedures.

Each participant in the project is responsible for becoming familiar with the work assigned to him or her, and with the test methods and other procedures he or she will be performing. Every professional and technical

employee will have at his or her desk a copy of the Corps of Engineers Handbook for Concrete and Cement, and keep it current with quarterly supplements. Testing will follow these procedures, or other CTD approved procedures for use temporarily prior to inclusion of the procedure in the Handbook, without change unless modifications for specific research purposes are expressly directed. Testing will also follow approved procedures for operating specific equipment. These procedures will be followed in research projects where they are applicable, as determined by the PI and project plan reviewers. Briefing on the contents of and responsibilities assigned in the RPP will be project-specific training, provided for all participants in the project by the PI or other qualified person.

All participants are responsible for keeping records of their work, as required in the applicable Research or Technical Project Plan, and by the RQM System. More information about record-keeping responsibilities appears in Section VI.

IV.D. Data Acquisition and Record Keeping

Each principal investigator is responsible for assuring the quality of the data acquired in the course of his or her project to this extent: the PI will review data as they are acquired, or arrange for another qualified individual to perform this function, to assure compliance with record-keeping requirements and standard or other specified test methods and procedures. This applies to computer-controlled data acquisition as well as hand-written records and data sheets. All manual or automated calculations will be checked by a second individual before being included in reports.

All handwritten data sheets will include the following information:

1. Project Name
2. Date of testing
3. Time of testing
4. Name or initials of person performing tests
5. Name of PI
6. Testing machine used
7. Units of measure
8. Notes about unusual occurrences or trends observed
9. Specimen or material identification numbers

10. Data from each step of procedure (intermediate numbers, rather than just final or calculated result). An example of this is data from compression testing, which will include sample dimensions and total load, as well as calculated strength value.

Data should be kept on standard forms or in a log book, rather than on miscellaneous sheets of paper. Do not erase data; instead, draw a line through data to be corrected and write corrected value. Some sponsors will require standard forms. The PI will see that required forms exist and are provided to people performing the tests before testing begins.

Each PI is responsible for keeping copies of the relevant data in project files. Some projects will require a central file, where duplicate copies of data from all tasks of a project, and all co-PI's and their collegues and assistants, are maintained together. This will be required by pre-arrangement between sponsor and PI, and stated in the initial RPP for the project.

For those projects requiring central Project filing, the file will be kept in the Group to which the PI belongs. Required documents for this file may include:

1. Data sheets and test records;
2. Quarterly or other periodic reports;
3. RPP's and amendments;
4. General correspondence and correspondence establishing or changing task descriptions or specifications;
5. Records of transmittal of data or reports (usually letters);
6. Documention of phone conversations or meetings;
7. Trip reports if required.

Other items may be required by a sponsor, as arranged at the outset of the project. These will be "Lifetime" files maintained for the lifetime of the project, which may be several years.

For all projects using computer-controlled data acquisition, the PI is responsible for maintaining at least one back-up copy of each data file, tape, or disk.

Technicians are encouraged to keep a log book, recording the specimens by test, and maintaining the data in the form described in Section IV.D.

Other types of records, which are not project specific, are kept in the central Division files. This includes calibration and maintenance records, computer software abstracts, and other documents. These are listed in Appendix D.

V. Sources and Procurement of Equipment and Materials

V.A. Government Procurement System

The system of procurement in effect at the Waterways Experiment Station follows rules established by the Department of the Army to assure the opportunity for competition among vendors. This system is operated by the WES Contract Branch, Contracting Division, and is extensively documented in that office. Any CTD employee who has questions about procurement procedures is encouraged to make inquiries directly to Contracting Division.

General guidelines for procurement procedures are outlined for WES employees in Station Regulation (SR) No. 715-1-1, which is available from Contracting Division. A copy of this SR is maintained in CTD central files.

V.B. Equipment Specifications.

When a project requires purchases of equipment or instrumentation, the PI is responsible for determining the specifications which that equipment must meet. SR 715-1-1 states: "Operating personnel will be responsible for establishing requirements, rendering assistance in preparation of specifications and determining that requirements of the specifications are met." If the PI determines, by observing or testing the equipment, that specifications are not met, the equipment is returned to the vendor by arrangement between Contracting Division and vendor at the PI's request.

V.C. Research Materials

Many research projects will require that specimens are prepared by CTD personnel, and that materials to be used in such specimens are chosen by CTD personnel to meet certain performance requirements. An example of this is proportioning a concrete mixture to attain certain levels of compressive strength, density, or other properties. In this type of project, the PI and colleagues will determine the specifications for component materials, as described in V.B for procurement of equipment. Depending on the nature of the material and project, these materials may be acquired directly from the sponsor or from another source (such as samples obtained from manufacturers). All such materials, from every source, will be identified and numbered within the CTD Materials Management System, described in Section VI.B.

Materials to be used in preparation of research or test specimens will be tested first, by standard methods, to determine that they meet the specified criteria for the project. Chemical analyses of cements and inorganic

admixtures are examples of this. Usually, the results of such analyses will be compared to those of tests of similar materials. The PI will specify the tests to be performed in the initial RPP or in a subsequent amendment or plan, as described in Sections III and IV.

V.D. Test Materials

Materials sent to the CTD for routine tests undergo no testing other than those required by the sponsor. However, the CTD employee responsible for the technical project will examine all such materials, to determine that they have been properly identified and described. This examination may require consultation with the responsible employee's supervisor or another individual with the expertise necessary to verify material descriptions. This is to avoid inaccurate descriptions of aggregates, as many rock types are outwardly similar; of admixtures, which may be labelled as cements; or of other materials.

VI. Identification and Control of Materials and Specimens

All materials received in the CTD for routine testing, for use as a component of specimens prepared in research projects, or for use separately in a research project, must be uniquely identified. The identifier is the "name" of that material, and is used in all subsequent references to that material. For example, a cement received in May 1985 was tested by chemical methods in July 1985, and used in research projects in the Concrete and Grout group in July through December 1985. Having a number assigned to this cement allowed the PI to keep simple records of its testing and use, simplified communication between PI and technical staff members, and avoided confusing this cement with another of the same type received in September of that year.

VI.A. Previous Materials Check-In System

Through FY 86, records of research and test materials were maintained by hand in log books and card files in the Materials and Concrete Analysis Group (M&CAG). The procedures for numbering specimens were described in Memorandum For All Concerned (MFAC) 84-15. The original documentation from receiving of any material through September 1986 should be available in those records.

VI.B. Materials Management System

Beginning 1 January 1987, all materials for testing and research are checked in by the same numbering system as was used previously, but in records maintained in data base files accessed by an HP 150 computer in the M&CAG. The PI or other designated responsible individual must assure that every material for testing, or to be included in research specimens, is checked in within two weeks of its arrival in the CTD. The operator of the check-in system assigns a number to the material, according to the description provided

by the PI. In other words, the PI must identify it as a research cement, or expansive admixture, for example, after which the system operator can assign an appropriate number which is the unique identifier for that material.

A description of the Materials Management System is kept in the CTD files. The PI or other designated individual will complete the receiving forms to be provided to the Materials Management system operator, giving all required information about the material. Copies of receiving forms are provided in Appendix B (WES Form No. 2391 and 2392).

VI.C. Identification and Control of Research and Test Specimens

Most research projects will require that specimens are created in the CTD for controlled testing and analysis. For all such projects, the PI will define the numbering system to be used for all specimens at the outset of the project, usually in the initial RPP or in a subsequent amendment. Definition of this numbering system is required before testing of the specimens can begin. In some cases, the numbering system will be determined by the sponsor. Identifiers as assigned through the Materials Management System will be used in testing programs when this is practicable. Technicians are required to keep records using these numbers, and cannot complete their tasks unless the numbering system is clearly defined.

VI.D. Identification and Control During Handling

VI.D.1. Identification

Whenever possible, numbering tags will be affixed to specimens at the time of casting. In other cases, specimens will be clearly marked with indelible ink or paint. If the specimen is too small for such marking, another appropriate system of marking will be devised by the PI or other designated individual, e.g. plastic or similar containers can be marked with paint and the specimen placed within.

All research or test specimens, and samples of materials, will be marked or otherwise identified at all times. This requirement includes all materials in laboratories or test areas, except when current operations prohibit such marking (such as when aggregate is spread on the floor for drying). All storage containers will be marked, even if used for only a short period of time. This marking will be on the container (not only on the lid) and will include at least the specimen or material identification number, and the name of the person responsible.

The unique identifier for each material, assigned when it was received, will be used to refer to that material in all subsequent handling, such as when subsamples of it are provided to Cement and Pozzolan or Petrography Units for analyses. This number also will be used to identify the material if it is shipped off Station.

The number assigned to each specimen as described in VI.C will be used in the same way, and will be used tc label any segment of that specimen through all subsequent handling and testing.

VI.D.2. Control of Specimen Condition

Specimens of grout and concrete will be handled in such a manner that the condition of the specimen is not changed between curing or storage and testing. As an example, specimens cured wet will not be allowed to dry between time of removal from storage chamber and time of testing. Likewise, specimens stored at elevated or lowered temperature will not be allowed to equilibrate to room temperature, unless this is stated in the test method being followed.

Testing of specimens in the proper condition will require careful scheduling of tests, to assure that specimens are not removed from their storage condition too long a time before being tested.

VI.E. Discarding Specimens

No specimens or component materials will be discarded until a project is completed, except for fragments of specimens tested to destruction, which are discarded unless they are required for additional analyses. The PI is responsible for assuring that no specimen or material is discarded unless all co-PI's and others involved in the research have completed all intended tasks, unless such disposal is specifically directed in the project plan. This is critical for large projects involving several CTD professionals, all of whom shall be consulted before specimens or materials are destroyed.

Upon completion of a task or project, the PI and his/her colleagues should determine the status of specimens and materials. Those to be maintained in long-term storage shall be marked as such, and labeled as described in Sections VI.C and D (including name of responsible individual). All other materials should be discarded soon after completion of the project, to avoid build-up of out-of-date and unneeded specimens and materials in laboratory areas.

VII. Evaluation of Materials, Items, and Activities

VII.A. Evaluating Research Materials Prior to Use

Before beginning a research project, the PI or another designated person is responsible for assessing the identification and suitability of any materials acquired for that project. For materials to be used in preparation specimens, this includes inspection to verify that the material meets specifications. It may entail testing of chemical composition or physical properties. Although the testing and inspection may be carried out by a

technical employee, the PI is ultimately responsible for this evaluation. In all records of materials testing and verification, the material will be identified by the unique number assigned to it when it was received.

VII.B. Evaluating Suitability of Measuring Devices

When a new measuring device is received, the appropriate Group or Unit Chief will assign an individual primary responsibility for that item. Lists of measuring devices and people responsible for operation and maintenance are kept in the central Division files, and are updated annually in conjunction with performance appraisals. The person who instigated the ordering of that item, or an individual assigned by the appropriate Group or Unit Chief, is responsible for evaluating its suitability for its intended use. That individual will notify the QA Manager of the established schedule for calibration and verification. No test equipment will be operated until its calibration has been verified, and a schedule for calibration/verification has been established.

Frequency of calibration or verification also is specified in the central Division files for each measuring device. The system of calibration and verification is described in Section VII.D. The person having responsibility for the item, as described in the previous paragraph, will calibrate, or have calibrated, or verify the calibration of, that item before it is put into service. The PI will check to see that the item has been verified before starting work on a project in which it is used. Work will be performed only with measuring devices that have been verified and meet calibration tolerances.

VII.C. Measuring Devices, Verification, and Calibration

To the extent possible, testing equipment in the CTD is calibrated and verified to conform to standards established by the National Bureau of Standards (NBS). This also applies to equipment to control areas where the environment is maintained under fixed conditions of temperature, or humidity, or both. Personnel of the Cement and Concrete Reference Laboratory (CCRL) of NBS inspect and verify or indicate need for calibration of testing equipment in the CTD every 2 years, as they have since 1948. CTD personnel perform interim verification activities, and calibration and verification of other equipment not covered by CCRL, as required in VII.D.3. Definitions are in Appendix A.

VII.D. Records of Measuring Devices, Verification, and Calibration

1. Equipment Records. Individual files are maintained by the QA manager in central Division files for all CTD measuring devices requiring verification of calibration. Data sheets, entitled "Instrument Inspection Record," (WES Form 2382 in Appendix B) are used to document conformance of measuring devices

to NBS or other Standard specifications. These records give the name and serial number of each measuring device, and name of the individual responsible for and qualified to operate it. Further, they report the date and procedure for normal verification/calibration, and provide space to describe action to be taken if the device is not accepted.

Form 2382 shall be used for equipment verified or calibrated at invervals of one week or longer. For equipment or instruments checked more frequently, Form 2381 may be used, as long as the device remains within the allowed tolerances. For example, if a device requiring "Verify Before Use" is in use daily for some interval, Form 2381 would allow the device to be checked four times and documented on a single page. Any device found to be out of calibration requires Form 2382 for documentation. These forms are in Appendix B.

The person who calibrates or verifies the equipment shall provide copies of these forms to the QA Manager, upon completion of the calibration or verification procedure.

2. Certificates of Verification. The QA manager will keep in the central Division files up-to-date certificates of verification or calibration for each device requiring verification or calibration by sources other than CTD personnel. CTD individuals responsible for measuring devices falling under this category shall be responsible for obtaining the required certificate and providing it to the QA manager for filing.

3. Verification by CTD Staff.

a. Schedules. Verification or calibration, whether conducted by CTD staff or by others, shall be performed on the regular schedule which is dictated by the Instrument Inspection Record kept in the central Division files. Each measuring device shall be verified or calibrated in accordance with the standard methods given for it. Copies of these procedures are also kept in the central Division files, and shall be referred to whenever a verification is being conducted. Whenever a verification or calibration has taken place, the Instrument Inspection Record (WES Form 2381 or 2382) kept in the central Division files shall be updated, through cooperation between responsible individual and QA Manager.

b. Responsible Individuals. Proper maintenance of measuring devices with periodic checks on their performance is necessary to minimize the contribution of experimental errors, and to approach the accuracy that the devices are capable of delivering. Verification and calibration is the responsibility of the personnel designated by the Group or Unit Chief, as described in Section VII.B. Apparatus used for calibration or verification shall be operated only by those people designated to do so.

c. Tags. Each measuring device within CTD which requires periodic verification or calibration shall bear one of the CTD Verification Tags which are shown in Appendix C, and described below. One form of the tags must be visible on the device at all times.

(1) CALIBRATION. This tag is to be displayed on a device after each calibration. It states by whom it was calibrated, their organization, the date the calibration was completed, and references the specific file in the central Division files where the certificate is kept.

(2) PERIODIC VERIFICATION. This tag is displayed along with the calibration tag to show that the device has been verified within the dictated verification period. It states by whom it was verified, the date, and the next verification date.

(3) VERIFY BEFORE USE. This tag is permanently displayed on each device that must be verified before each use. It also states the standard by which it should be verified.

(4) CALIBRATION VOIDED, DO NOT USE. This tag must be displayed on any measuring device that is not currently within calibration. It states who voided the equipment, and the date it was voided.

4. Out of Verification Procedures. Whenever a measuring device fails a verification, the person designated as responsible for that device must take the necessary action to see that it is recalibrated. Immediately, a CALIBRATION VOIDED, DO NOT USE tag shall be placed on the device by the responsible individual or the QA manager. The chief of the Group or Unit in which this device is located shall be notified that the device is no longer in calibration. A device so marked shall not be used, unless its use is approved in writing by the Chief, CTD, informing all people involved of this decision. All such memos shall be maintained by the QA manager in the appropriate equipment files.

a. Lack of Calibration Device. If an item cannot be calibrated or verified due to a lack of equipment to perform the calibration or verifications, the individual responsible for that equipment will complete WES Form 2383, "Apparatus/Device Needed for QA Calibration/Verification," and provide copies to his/her supervisor; the QA manager; and the Chief/CTD, who is responsible for acting on or designating another individual to act on this request for calibration equipment. A copy of WES Form 2383 appears in Appendix B. Copies are available from the QA manager.

b. Data from Device Out of Calibration. If data were generated during a period in which the device may be assumed to have been out of calibration, the person responsible for the device will complete a

nonconformance report, as described in Section X. Recalibration is documented in a Corrective Action Report (Section XI). Data obtained from a measuring device found to be out of calibration must be analyzed for the effect of an out of calibration device having been used.

VIII. Management Assessment of Quality Practices

The Group and Division Chiefs will check periodically with each principal investigator or project leader on each research project, to determine technical progress and adherence to quality practices. This process may include: interviews and discussions; reviews of monthly, quarterly, or other reports; spot checks of test procedures being used and data records being maintained for the project, including those maintained by technical assistants; and performance appraisals. The ability to adhere to the requirements of the project or of the RQM System, by all persons at all employment levels, shall be documented in the PI's annual performance appraisal.

IX. Computer Hardware and Software

IX.A. Equipment List

A list of computer hardware and software currently in use in the CTD is maintained in the Evaluation and Monitoring Unit. This list serves as an index to all such equipment throughout the Division. Each person who acquires computer equipment or software is responsible for registering that equipment in that list.

IX.B. Software Documentation

All software in use in the CTD, whether purchased or generated by or for a CTD employee or specific CTD project, must be documented. In addition to Users' Guides, which are maintained by the Unit aquiring the software, each program must be documented on WES Form 2370, entitled "Concrete Technology Division, Computer Program Abstract." The person who purchases or instigates development of the software is responsible for completing the abstract form. It is most important for internally generated programs, for which there are not published descriptions.

A file of completed Computer Program Abstracts is maintained in the central Division files. A copy of Form 2370, and instructions for its use, are in Appendix B. Copies are available from the QA manager.

X. Identifying, Documenting, and Correcting Nonconformances

X.A. Definition of Nonconformance

A nonconformance is a condition of a procedure, characteristic, or documentation of these that makes the quality of an item or validity of

resulting data questionable or unacceptable. It is "nonconforming" to standards, specifications, or procedures of the quality assurance system in practice in the laboratory.

X.B. Identifying Nonconformances

X.B.1. Examples

In research, many occurrences deviate from what the researchers originally expected. Developmental procedures that go other than as expected are not nonconformances. Such unexpected events must be documented, and the researchers notes or memos about the project are the appropriate place.

Nonconformances are occurrences, either deliberate or accidental, which are not technically or scientifically justifiable. Examples are:

* use of test equipment that is later found to be out of calibration;

* use of an incorrect test procedure, or not following a specified procedure;

* use or testing of an improperly labelled or misidentified material;

* unauthorized changes in storage or test conditions;

* inadequate recording of data or test conditions;

* systematic errors in computation, which may indicate problems in reporting data.

This is not a complete list, but should give sufficient examples so that nonconformances can be readily identified.

X.B.2. Questions about Age at Testing

Questions have arisen from time to time about testing concrete specimens at ages other than those specified in test procedures. CRD-C 14-85 (ASTM C 39-84) specifies tolerances in specimen age for testing, to 90 days. Tolerances for ages up to 365 days have been specified for standard tests within the CTD (in MFAC 333-M, dated 22 July 1952). These tolerances are summarized in Table X.0.

Table X.0.

Time Tolerances for Testing Concrete Specimens

Test Age	Permissible Tolerance
24 h	±0.5 h (2.1%)
3 d	2 h (2.8%)
7 d	6 h (3.6%)
28 d	20 h (3.0%)
90 d	2 d (2.2%)
180 d	2 d (1.1%)
365 d	5 d (1.4%)

Longer term storage generally applies only in research and developmental programs (is nonstandard), and permits similarly increasing age tolerances in testing.

Deviations from these test ages should be avoided whenever possible. However, scheduling and funding constraints may necessitate such deviations (such as testing at 29 days age). These deviations must be documented in research notes or memos, but do not require nonconformance reports.

X.B.3. Questions About Constant Weight

Questions have also arisen about the meaning of the instruction "dry to constant weight." CRD-C 137-86 (ASTM C 88-83) specifies tolerances as follows: "Constant weight will be considered to have been achieved when weight loss is less than 0.1 percent of sample weight in 4 hr of drying.

X.B.4. Responsibilities

Every CTD employee is responsible for maintenance of quality practices to minimize nonconformances. Any employee who detects an apparent or actual nonconformance will notify the PI of the project, as well as the Chief of his or her own Group or Unit. The Group or Unit Chief, in cooperation with the PI of the impacted project, determines who must document the nonconformance. This person may be the PI, the individual responsible for equipment in question (as outlined in Section VIII), the QA manager, or another appropriate person.

X.C. Nonconformance Reports

X.C.1. Purpose of the Nonconformance Report

It is important to keep in mind the quality-related purpose of documenting a nonconformance. The nonconformance report is a communication tool, to point out that we need to establish procedures that will help us

avoid recurrence. Putting it on the Nonconformance Report form highlights the fact that a change is needed, and that the concerned supervisors need to decide what procedures will be followed in the future.

X.C.2. Disposition of Nonconforming Items

Equipment, specimens, materials, or data identified as nonconforming will be clearly marked as such by the QA manager in cooperation with the PI or Group or Unit Chief as appropriate, to avoid further use or intermingling these items or data with those that conform to specifications or requirements.

X.C.3. Records and Closing Out a Nonconformance

Nonconformance reports are maintained in the central Division files. They are numbered consecutively for each fiscal year by the QA manager. They must be signed by the PI of the impacted project. Action taken to correct the nonconformance, usually within one month of the occurrence, will be documented by the QA manager, who then closes out the condition of nonconformance (see Section XI).

A Nonconformance Report form is included in Appendix B.

X.D. Avoiding Recurrence

Communication is the key to avoiding recurrence of nonconforming conditions or occurrences. Nonconformances, and the root causes of them, should be discussed in project meetings. Appropriate nonconformance reports should be circulated among all CTD employees who have or should have concern about the occurrence. This includes: technical employees who use affected equipment or perform the same or similar tests; other members of a project team whose activities may be affected by the time delay or other delays accompanying the necessary corrective action; the Unit, Group, and Division Chiefs, and any other individuals for whom they recognize a connection to the nonconformance.

Decisions about what to do with data made questionable by a nonconformance will be made specifically for each case. The decision-making process will involve the PI, the project staff, the Unit Chief, and the Group Chief, who has the ultimate responsibility for these decisions.

XI. Corrective Action

XI.A. Definition of Corrective Action is given in Appendix A.

XI.B. Documenting Corrective Action

Documentation of corrective action can be an Office Memorandum (WES Form 1741), a Disposition Form (DA Form 2496), or a Memorandum for Record, as are described in Section IV. If the corrective action is taken to close out a pending nonconformance report, the corrective action memo will refer to the nonconformance report by number.

Copies of corrective action memos will be maintained in the CTD central files and in the PI files.

Every nonconformance report requires close-out by corrective action memo, as does out-of-calibration status for any piece of equipment. However, corrective action memos should be written for any activity to correct a problem with potential serious impact on quality of data, even if no nonconformance report preceded the correction. Copies of corrective action memos addressing nonconformances shall be sent to all persons notified of the nonconformance (Section X.D).

XI.C. Responsibility

The principal investigator or project leader of each project has responsibility for documenting corrective actions that are specific to the project. Other corrective actions, such as those involving a piece of equipment or application of test procedures that affect more than one project, are the responsibility of the Group Chief or other designated individual. The QA manager shall review and sign documentation of corrective action to close out the nonconformance or other condition.

XII. Training and Certification

XII.A. Technical Training

All employees in engineering and scientific positions in the CTD are qualified for those positions according to requirements of the U.S. Office of Personnel Management. Resumes of their academic qualifications and professional experience are maintained in personnel files. Additional training is available to such employees (Section XII.C).

All technical employees of the CTD are trained to perform the tasks assigned to them. This training includes but is not limited to:

1. Having and referring frequently to a copy of the Handbook for Concrete and Cement, which includes Corps and ASTM standard test methods (see Section I.D);

2. Documented reader acknowledgement of specific test methods performed by each employee (WES Form 2379, in Appendix B);

3. Demonstration of techniques by other previously trained and qualified technicians, engineers, or scientists;

4. Attending a Concrete Technician Certification course offered by the American Concrete Institute through WES and becoming Certified Concrete Technicians upon successful completion of that course (selected technicians);

5. Attending a Concrete Construction Inspection course, offered at the Waterways Experiment Station, at least once every five years;

6. Attending formal training workshops in the CTD, conducted by instructors from private industry in specialized areas, such as strain-gage application (selected technicians);

7. Attending informal training in the CTD, including viewing instructional video tapes from the American Concrete Institute on appropriate subjects, as directed by Group Chiefs;

8. Personal instruction from engineers or scientists and the Unit Chiefs in new testing methods and techniques, or comprehensive training of this nature for new employees.

Attendance records of training offered in the CTD shall be maintained in the Division files. Records of project-specific orientation, and planning sessions which constitute training, shall be maintained in project or Group files.

XII.B. Certification of Technical Ability

A Certification of Technical Ability (WES Form 2380) is kept in the central Division files for each employee who performs technical work. These are completed and signed by the appropriate Group or Unit Chief, and list the procedures and equipment for which each employee is qualified. They are updated annually as part of the Performance Appraisal procedure (see below).

Job descriptions for each employee include a list of the tests he/she will be required to perform. Each employee undergoes an annual Performance Appraisal and at least one intermediate review, during which supervisor determines whether or not the employee is meeting the Performance Requirements written for that job, and certifies the quality level of performance. Job descriptions, Performance Standards, and Performance Appraisals for each employee are in the supervisor's files, and in personnel files for every Government employee.

XII.C. Other Training

Any employee may request training from either government or non-government sources, subject to the approval of the Group Chief. Such approved

training is funded by CTD sources, and approval is dependent upon the Group Chief determining that such training will improve or enhance the employee's performance.

XII.D. Quality Assurance Training

Implementation of the RQM System include the requirement that every employee sign a Reader Acknowledgement sheet (WES Form 2379), stating that they have read and understand this manual documenting the Research Quality Management System. These Reader Acknowledgements are maintained in the central Division files. The QA manager and other appropriate individuals conduct seminars for all employees to clarify and expedite continuous implementation of the practices described here. Additional training sessions are conducted for individual or small groups of new employees, contract employees, and others as needed to familiarize them with the requirements of the RQMS;, and on subjects of noncompliance or nonconformance for present employees. These sessions will be conducted by the QA manager and by other individuals designated by Group Chiefs or the Chief, CTD.

XIII. Audits and Inspections

Audits and inspections will be performed in the CTD by the QA manager, by other qualified WES employees, or by QA representatives from sponsors. These audits and inspections will be performed to accomplish the following goals:

1. Verify that the RQM System is continuously implemented and that its practices are adequately documented (e.g., programmatic audits);

2. Verify through examination and evaluation of objective evidence that quality assurance program elements conform to specified requirements (e.g., implementation audits);

3. Assess the effectiveness of controls established and the verification activities;

4. Report audit and inspection findings or deficiencies to all necessary levels of management for the identification of root cause, corrective action, and the initiation of measures to prevent recurrence;

5. Verify that corrective action has been planned, initiated, completed, and is adequate;

6. Develop and maintain a tracking and trending system for audit findings to assure that all findings are appropriately addressed in a timely manner and that audit and inspection results are incorporated into the implementation of the RQMS.

XIII.A. External Audits

A sponsor may require that the quality of research or testing accomplished in the CTD be documented by audits, performed by quality assurance inspectors employed by that sponsor. This requirement will be established by aggreement between the sponsor's representative and the Chief, CTD, and higher level WES management as appropriate, before a project is begun. The frequency and intended nature of these audits also will be established by prearrangement between sponsor and CTD management.

External audits will follow the general guidelines for audits listed above and in Section XIII.B and D.

XIII.B. Internal Audits

Internal audits shall be conducted to assure that procedures and activities comply with the overall RQM System. The CTD QA manager or other qualified individual will perform audits of contractors if this is required for a specific project, to assure that these contractors conform to similar QA practices.

In conducting internal audits, the CTD QA manager is responsible for:

1. The development and implementation of an audit and inspection program, including the schedules and performance of audits, and the qualification and certification of auditors and inspectors.

2. Annual issuance of a schedule of audits to be conducted, including both internal and external audits. Additional audits will be scheduled and conducted as required to monitor project activities, or to provide additional information related to unusual events or quality problems.

3. Assurance that personnel assigned as inspectors are independent of any direct responsibility for the performance of activities being audited.

4. Reviewing and approving audit plans, checklists, and reports prior to use or issue.

5. Development of an audit plan, direction of the audit, and preparation and issuance of the audit report. The manager also is responsible for the review and follow-up of corrective action of audit findings.

XIII.C. Inspections

In addition to regularly scheduled audits, additional inspections will be conducted as necessary to provide continued monitoring of quality practices or for any of the following reasons:

1. When significant changes are made in the RQM System;

2. When it is suspected that the quality of an item or practice is in jeopardy due to deficiencies in the QA program;

3. When a systematic, independent assessment of program effectiveness is desired;

4. When verifying implementation of required corrective action;

5. As required by agreement between CTD management and sponsors.

Unannounced inspections shall be conducted by Chiefs of SL, CTD, CTD Group or Unit, the QA Manager or his/her designee, or jointly by two or more of these people. Inspections will be documented by Memorandum for Record.

XIII.D. Audit Reports, Responses, and Records

1. Audit Reports.

Conditions requiring prompt corrective action shall be reported immediately to CTD management of the audited Division, Group, or Unit. The audit report shall be signed by the audit team leader and issued to the affected management for review, assessment, and initiation of appropriate action. The audit report shall, at a minimum include:

a. Description of the audit scope.

b. Identification of the auditors.

c. Identification of persons contacted during the audit.

d. Summary of audit results, including a statement regarding effectiveness of the RQMS elements which were audited.

2. Audit Responses

The audited Division, Group, or Unit shall respond in writing to the audit findings identified in the audit report by a requested date. This response shall include a determination of root cause, and a schedule for compliance to RQMS. The response shall be submitted to the person or organization that conducted the audit, and to the Chief, CTD.

Follow-up action shall be taken by the auditing organization to verify that corrective action is scheduled and in compliance with the RQMS.

3. Audit Records

Audit records shall be maintained in the central Division files, and shall include audit plans, audit reports, written replies, and the records of completion of corrective action.

XIV. Records

Original project records or a legible copy, suitable for use and reproduction as an original, should be maintained in the appropriate file or files as specified below for the life of the project, or not less than five years. Certain quality assurance records may be kept permanently as specified. Project sponsors may also require permanent retention of certain project records. When this is the case, it will be established at the start of the project.

XIV.A. Central Division Files

The central Division files will include the documents outlined in Appendix D, CTD QA File System. These documents are permanently retained.

XIV.B. Central Project Files

The Central Project files are maintained for certain projects, as specified in the RPP, or amendments, for that project. Records will include the following, maintained for at least five years or the life of the project.

1. Research and Technical Project Plans (RPP and TPP)
2. Data sheets
3. Nonconformance documents
4. Corrective action documents
5. Peer review documents
6. Reports to sponsors
7. Other memos, as described in Section IV

XIV.C. Principal Investigator Files

Records kept by the PI may include any project records deemed necessary. Information not kept in other files that should be kept by the PI is listed below:

1. Telecon and other memos recording communication between sponsor and PI, or PI and other staff elements;

2. Correspondence with the sponsor;

3. Transmittal records (usually cover letters) for data or reports, required for all data or reports provided by employees of the CTD to sponsors.

APPENDIX A

DEFINITIONS

1. Audit (QA) - A planned and documented activity performed in accordance with written procedures or checklists to determine, by investigation and examination or evaluation of objective evidence, the adequacy of and compliance with the requirements of the QA program, established procedures, instructions, drawings, contractual requirements, and other applicable documents, and the effectiveness of implementation.

2. Audit Finding - A condition determined, as a result of an audit, either to be in compliance or noncompliance with the QA Program or the QA Requirements Documents.

3. Auditor - An individual who performs any formal portion of an audit and who has demonstrated completence for auditor qualification in accordance with the QA Program.

4. Calibration - The process of correcting the accuracy of a measuring device to bring it within acceptable limits of error.

5. Certify - To determine, verify, and attest to in writing (i.e., document) the qualifications of personnel, processes, procedures, data items, or material, in accordance with stated requirements.

6. Certification - The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

7. Characteristic - Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

8. Conform - To correspond in form, manner, or character to specified standards or requirements as previously determined.

9. Contract - A mutually binding legal relationship obligating the seller to furnish supplies or services (including construction) and the buyer to pay for them.

10. Contractor - One that contracts to perform work or provide supplies.

11. Corrective Action - An activity taken to rectify a condition adverse to quality, and where possible, preclude recurrence of that condition.

12. Data Analysis - The initial step of data reduction as well as broad level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters.

13. Document - (noun) Written or printed information or evidence, specifically in QA, any written, printed, recorded, pictorial, or processed information describing, defining, specifying, prescribing, reporting, or

certifying activities, requirements procedures, data, or results (See QA Record). (verb) The act of creating a document; to furnish documents or documentary evidence.

14. Documentation - Collective body of documents

15. Indoctrination and Training - Includes all of the actions necessary (e.g., classroom sessions, on-the-job training, required reading assignment, etc.) to assure that personnel assigned to manage or perform activities affecting quality are familiar with and understand the purposes, administrative controls, and interfaces applicable to their work assignments.

16. Inspection - Documented examination or measurement by a qualified, independent party to verify that an item or activity conforms to specified requirements so that the resultant data are of known quality.

17. Inspector - A person who performs inspection activities to verify conformance to specific requirements.

18. Internal Audit - An audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

19. Measuring Device - An instrument used to measure, gage, test, inspect, or otherwise examine items or events to control or acquire data, or determine compliance with specifications.

20. Nonconformance - A condition of a procedure, characteristic, or documentation of these that makes the quality of an item or validity of resulting data questionable or unacceptable. It is "nonconforming" to standards, specifications, or procedures of the quality assurance system in practice in the laboratory.

21. Peer Review - A formally documented review of technical material performed by individuals who are independent from the organization that performed the work and have technical expertise at least equal to that of the performing individuals. A peer review on a report may be conducted when underlying technical conclusions are based, at least partially, on subjective judgements or application of existing theories on new ideas.

22. Personnel Qualifications - The characteristics or abilities gained through education, training, or experience as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

23. Project Plan - A written description of the activities required to achieve the goals or objectives of a program. It describes the strategy to be followed and major actions to be taken to achieve those objectives. The plan

addresses project-related elements including program interfaces, schedule, major milestones, budget, technical control, quality assurance, and program control.

24. Quality - May be regarded, in the technical sense, as definable, controllable, measurable, and verifiable properties, features, or characteristics of a study, investigation, design, material process, or product. Quality is frequently defined in the physical sense as the fitness of a product or service for intended use. Conformance to established regulations and requirements is the definition of a quality in a licensing and contractual sense.

25. Quality Assurance (QA) - Planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. When the product is a report of a significant study or investigation, quality assurance comprises those planned and systematic actions necessary to provide adequate confidence in the validity and integrity of the reported data, methods, procedures, conclusions, interpretations, and recommendations, and in the protection, retrievability, and possible reproducibility of the data.

26. Quality Assurance Program - A written, documented description for an organization's total concept, requirements, and scope of effect for achieving and verifying quality. The program sets forth quality assurance policy, objectives, requirements, authority, and responsibility, organization, methods, and activities required to implement and assess the adequacy and effectiveness of the program.

27. Quality Assurance Record - A completed document that furnishes evidence of the quality and completeness of data, items, and activities affecting quality; documents prepared and maintained to provide objective evidence and demonstrate implementation of the quality assurance program.

28. Technical Data - Recorded scientific or technical information, regardless of form or characteristics. It may, for example, document research, experimental, developmental, test, demonstration, or engineering work; or be usable for characterizing an area or a site; for defining a design or process; or for procuring, producing, supporting, maintaining, or operating material or equipment. Technical data may consist of experiment and engineering data, design specifications, performance requirements, computer software, and all related documents, geophysical notes and data, laboratory data, records of data reduction and analysis, and the results of peer review. The data may be in any form, such as laboratory notebooks, field notes, drilling logs, geologic survey notes, graphics, engineering, drawings, any photographic media, magnetic recordings, computer printouts, specification and process sheets, catalog information, reference standards, manuals, and technical reports.

29. Technical Review - A formally documented review of technical material performed by individuals independent of those responsible for the work but who may be members of the organization within which the work was done. A technical reviewer has expertise at least equal to that of the individuals who prepared the material under review. A technical review is performed for material that is within the current state of the art; the review is an objective evaluation of the technical content, based on well known and generally accepted standards.

30. Test Plan - A specialized form of an activity plan which addresses technical requirements and conditions for conducting a test or series of tests.

31. Verification - The process of establishing the accuracy of a standard or measuring device, or verifying that it is operating within the limits established through calibration.

APPENDIX B

FORMS

CONVERSATION RECORD

TIME	DATE

TYPE

☐ VISIT ☐ CONFERENCE ☐ TELEPHONE ☐ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.

ROUTING	
NAME/SYMBOL	INT

SUBJECT

SUMMARY

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE

ACTION TAKEN

SIGNATURE	TITLE	DATE

WATERWAYS EXPERIMENT STATION

Office Memorandum

To _____ Date _____

Subject _____

From _____

WES FORM 1 JUN 60 1741

CONCRETE TECHNOLOGY DIVISION
COMPUTER PROGRAM ABSTRACT

DATE:	PROGRAM NAME:	REVISION:	HOST COMPUTER:
PROGRAM TITLE			
PROGRAM DESCRIPTION:			
LIMITATIONS:			
KEY WORDS, PHRASES:			
ORIGIN/SOURCE:			
AUTHORS:			
PARENT PROGRAM:			
COMPUTER LANGUAGES:			
PROGRAM STATUS: ☐ CURRENT ☐ NEW ☐ REPLACEMENT ☐ OTHER: _____			
CLASSIFICATION: ☐ PROPRIETARY ☐ GOVERNMENT OWNED LIMITED DISTRIBUTION ☐ PUBLIC DOMAIN ☐ OTHER, SPECIFY		ANALYST: _____ PROGRAMMER: _____	

WES Form 2370
1 Sep 86

VERIFICATION:

- ☐ HAND CALCULATIONS, REF: _____
- ☐ CORRELATION WITH EMPIRICAL DATA, REF: _____
- ☐ COMPARISON WITH OTHER VERIFIED PROGRAMS, SPECIFY: _____
- ☐ PARAMETRIC SENSITIVITY ANALYSIS, REF: _____
- ☐ OTHER, REF: _____

DOCUMENTATION:

- ☐ USERS, REF: _____
- ☐ PROGRAMMER'S, REF: _____
- ☐ THEORETICAL, REF: _____
- ☐ SAMPLE PROBLEMS, REF: _____
- ☐ VERIFICATION, REF: _____
- ☐ JOURNAL ARTICLE, REF: _____
- ☐ OTHER, REF: _____

REFERENCES:

APPROVED BY: _____ DATE: _____

COMPUTER PROGRAM ABSTRACT
Instructions for Preparation

1. Program Name - initials or shortened form by which program may be identified.

2. Revision - numbered version of program such as 1.0, 2.0 or 3.0, or the date revised.

3. Program Title - actual program name or longer version from initials.

4. Host Computer - manufacturer of computer and model on which program will run.

5. Program Description - describe what the program does; how it is basically used; and any other information needed to determine what the program does.

6. Limitations - state any major limitations of the program such as amount of memory required to run program.

7. Keywords/Phrases - give the program language, list key phrases that give an idea of what the program does or is dealing with.

8. Origin/Source - company who employs the programmer. For proprietary programs, identify the organization responsible for program maintenance.

9. Authors - all persons who provided significant input to the development of the code in either engineering/scientific theory or in program design, the actual writing and finding of errors in the program.

10. Parent Program - name and version of the original program from which this program has been derived through revisions.

11. Computer Languages - language in which the program was coded. If non-standard, list compiler version also.

12. Status - current(running);new(just implemented);replacement(replaces a current obsolete program).

13. Classification - indicates who has access to program.

14. Analyst - individual assigned responsibility for preparing & submitting this abstract.

15. Programmer - individual assigned as programmer.

16. Verification - types of verification performed date on the program, with references.

17. Documentation - indication of the types of references maintained by the user organization.

18. References - bibliography of pertinent references for the program.

19. Approval - dated signature of manager indicating approval of the abstract content and program revision.

READER ACKNOWLEDGEMENT

I ACKNOWLEDGE THAT I HAVE READ AND UNDERSTAND THE FOLLOWING PROCEDURES:

A. _____ D. _____

B. _____ E. _____

C. _____ F. _____

NAME	TITLE	DATE	INITIAL
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
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15.			
16.			
17.			
18.			
19.			
20.			

WES Form 2379
1 Oct 86

CERTIFICATION OF TECHNICAL ABILITY

I CERTIFY THAT _____ (Name), A _____ (Title),

IS CAPABLE OF PERFORMING THE PROCEDURES AND/OR USING THE EQUIPMENT LISTED BELOW.

1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
16. Certifying Official Signature	17. Title	18. Date

WES Form 1 Oct 86 2380

TEST EQUIPMENT/DEVICE CALIBRATION/ VERIFICATION RECORD

Limit to one item per page

1. DATE	2. UNIT
3. EQUIPMENT/DEVICE	4. SERIAL NO.
5. DESCRIPTION	
6. QUALIFIED OPERATORS (as determined by Unit Chief)	
7. INTERVAL a. for _____ Calibration: _____ b. or _____ Verification: _____	
8. Check one: a. _____ Calibration	b. _____ Verification Record
c. DATE	d. BY
e. REMARKS	
9. Check one: a. _____ Calibration	b. _____ Verification Record
c. DATE	d. BY
e. REMARKS	
10. Check one: a. _____ Calibration	b. _____ Verification Record
c. DATE	d. BY
e. REMARKS	
11. Check one: a. _____ Calibration	b. _____ Verification Record
c. DATE	d. BY
e. REMARKS	
USE CORRECTIVE ACTION REPORT TO RESOLVE PROBLEMS	

WES Form 2381
1 Oct 86

INSTRUMENT INSPECTION RECORD

1. INSTRUMENT	2. SERIAL NO.

3. Check one

a. _____ CALIBRATION b. _____ VERIFICATION c. _____ MAINTENANCE CHECK

4. DATE	5. BY

6. PROCEDURE	7. CALIBRATION STANDARD

8. ACCEPTED (Check one)

_____ Yes _____ No

Complete Items 9 Through 11 If Not Accepted.

9. COMMENTS

10. HOW WILL SITUATION BE RESOLVED, AND WHEN?

11. CERTIFICATION

I certify that this instrument has been marked as unfit for use.

_____
Signature of Unit Chief

USE CORRECTIVE ACTION REPORT TO INDICATE RESOLUTION OF SITUATION.

WES Form 1 Oct 86 2382

APPARATUS/DEVICE NEEDED FOR QA CALIBRATION/VERIFICATION		1. DATE
Limit to One Item Per Page		
2. ITEM AND DESCRIPTION	3. TO BE USED TO CALIBRATE/VERIFY	4. SOURCE AND APPROXIMATE COST
5. SIGNATURE		

WES Form 1 Oct 86 2383

Concrete Technology Division Materials Management System

CORE SAMPLE CHECK-IN

1. DATE RECEIVED	2. DATE CHECKED IN	3. CTD ENGINEER
4. RESEARCH/TECHNICAL PROJECT PLAN		5. JOB NO.
6. MATERIAL	7. PIECES	
8. DATE SAMPLED	9. SAMPLED BY	
10. DRILL HOLE NO.	11. CORE DIAMETER	12. TOTAL NO. OF BOXES
13. DISTRICT/AGENCY	14. CONTACT NAME	15. PHONE: FTS _____ Commercial _____
16. PROJECT NAME	17. LOCATION	18. CONTRACT NO.
19. REMARKS		

20. FIELD IDENTIFICATION

(a) Box No.	(b) Depth ft to ft	(c) Elevation (mean sea level) Top	(c) Elevation (mean sea level) Bottom	(d) Materials Management System ID

WES Form 1 Feb 87 2391

(Continue on reverse)

20. FIELD IDENTIFICATION (Continued)				
(a) Box No.	(b) Depth ft to ft	(c) Elevation (mean sea level)		(d) Materials Management System ID
		Top	Bottom	

Reverse of WES Form 2391

Concrete Technology Division Materials Management System

MATERIALS CHECK-IN

1. DATE RECEIVED	2. DATE CHECKED IN	3. CTD ENGINEER
4. RESEARCH/TECHNICAL PROJECT PLAN		5. JOB NO.
6. MATERIAL	7. PIECES	8. LOT NO.
9. DATE SAMPLED	10. SAMPLED BY	11. TEST SPECIFICATION
12. DISTRICT/AGENCY	13. CONTACT NAME	14. PHONE: FTS _____ Commercial _____
15. PROJECT NAME	16. LOCATION	17. CONTRACT NO.
18a. CONTRACTOR	18b. CITY	18c. STATE
19a. SUPPLIER	19b. CITY	19c. STATE
20a. MANUFACTURER	20b. CITY	20c. STATE
21. REMARKS		

22. FIELD INFORMATION

(a) FIELD IDENTIFICATION	(b) MATERIALS MANAGEMENT SYSTEM OPERATOR/IDENTIFICATION	(c) FIELD IDENTIFICATION	(d) MATERIALS MANAGEMENT SYSTEM OPERATOR/IDENTIFICATION

WES Form 1 Feb 87 2392

Concrete Technology Division

NONCONFORMANCE REPORT

1. REPORT NO.	2. PROJECT NAME
3. RESEARCH/TECHNICAL PROJECT PLAN	4. PRINCIPAL INVESTIGATOR
5. DATE DISCOVERED	6. DATE REPORTED

7. NATURE OF NONCONFORMANCE	8. DESCRIPTION OF NONCONFORMANCE AND APPARENT CAUSE
___ Procedural Deficiency ___ Data Deficiency ___ Instrumentation Problem ___ Error ___ Other _____ _____	_____ _____ _____ _____ _____ _____

9. RECOMMENDED DISPOSITION	10. RECOMMENDED CORRECTIVE ACTION
___ Accept Deviation ___ Modify Plan/Procedure ___ Repeat Service/Activity ___ Terminate ___ Conditional Acceptance (state conditions) _____ _____	_____ _____ _____ _____ _____ _____ _____ _____

11. REPORTING PARTY	12. UNIT
13. PRINCIPAL INVESTIGATOR	14. DATE
15. UNIT CHIEF	16. DATE
17. GROUP CHIEF	18. DATE
19. QUALITY ASSURANCE MANAGER	20. DATE

USE CORRECTIVE ACTION REPORT TO INDICATE RESOLUTION OF SITUATION

WES Form 2393
1 Feb 87

DISPOSITION FORM

For use of this form, see AR 340-15, the proponent agency is TAGO.

REFERENCE OR OFFICE SYMBOL	SUBJECT

TO	FROM	DATE	CMT 1

DA FORM AUG 80 2496

PREVIOUS EDITIONS WILL BE USED

* USGPO 1986-490-003/43241

APPENDIX C

TAGS

VERIFY BEFORE USE

STANDARD USED_____

Orange

CALIBRATION VOIDED

DO NOT USE

VOIDED BY_____DATE_____

Red

CALIBRATION

CALIBRATED BY_____

ORG_____DATE_____

FILE_____

White

PERIODIC VERIFICATION

VERIFIED BY_____DATE_____

NEXT VERIFICATION DUE_____

White

SCHEDULED CALIBRATION

CALIBRATE:

____ WHEN TEST COMPLETED

____ WITHIN 3 MONTHS

SIGNED_____DATE_____

White

APPENDIX D

STRUCTURES LABORATORY
CONCRETE TECHNOLOGY DIVISION,
QUALITY ASSURANCE FILE SYSTEM

I. Primary Documents

A. Quality Program Plan

B. List of contractor procedures cross-referenced to elements of the contractor's quality program plan

C. Task Definitions
   1. Sponsor Definitions
   2. RPP and TPP Definitions
      a. Experiment Design Verification
      b. Technical Review

D. Procurement subcontracts and authorized changes
   1. Supplier Evaluations
   2. Verification of Subcontractor's Certifications

E. Laboratory Notebooks, Test Data Forms, etc.

F. List of special processes, related equipment, and qualified personnel

G. List of Activities requiring special training
   1. Concrete and Evaluation Group
      a. Evaluation and Monitoring Unit
      b. Concrete and Grout Unit
   2. Materials and Concrete Analysis Group
      a. Materials Properties Unit
      b. Cement and Pozzolan Unit
      c. Chemistry Unit
      d. Petrography Unit

H. Description of Training
   1. Concrete and Evaluation Group
      a. Evaluation and Monitoring Unit
      b. Concrete and Grout Unit
   2. Materials and Concrete Analysis Group
      a. Materials Properties Unit
      b. Cement and Pozzolan Unit
      c. Chemistry Unit
      d. Petrography Unit
   3. Research Group

I. Description of Calibration Program
   1. Calibration Stickers and Tags
   2. List of personnel authorized to apply and remove tags, markings, and labels indicating process and inspection status
      a. Concrete and Evaluation Group
         (1) Evaluation and Monitoring Unit
         (2) Concrete and Grout Unit
      b. Materials and Concrete Analysis Group
         (1) Materials Properties Unit
         (2) Cement and Pozzolan Unit
         (3) Chemistry Unit
         (4) Petrography Unit

J. Quality Assurance Training Records

II. Supplementary Documents

A. Inspection Procedures

B. Record Indexing System

C. Audit Procedures or Checklists

D. External Audit Results and Reports

E. Identification and Control of Items

III. Division Quality Assurance Records

A. Internal Audit and Inspection Reports

B. Software List
   1. Software Validation

C. Concrete and Evaluation Group
   1. Evaluation and Monitoring Unit
      a. Measuring Device List
         (1) Operators
         (2) Calibration Requirements
            (a) Schedule
            (b) Procedures
         (3) Calibration Inspection Records
            (a) Corrective Action Reports
      b. Design Reviews
      c. Nonconformance Reports
         (1) Corrective Action Reports

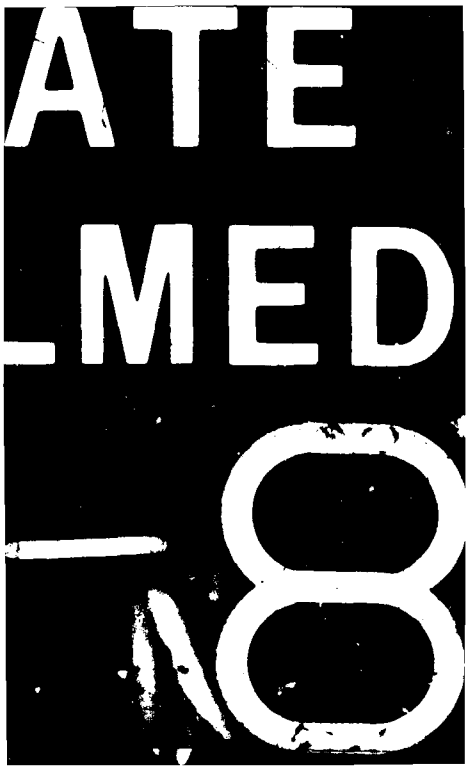
2. Concrete and Grout Unit
    a. Measuring Device List
        (1) Operators
        (2) Calibration Requirements
            (a) Schedule
            (b) Procedures
        (3) Calibration Inspection Records
            (a) Corrective Action Reports
    b. Design Reviews
    c. Nonconformance Reports
        (1) Corrective Action Reports

D. Materials and Concrete Analysis Group
    1. Materials Properties Unit
        a. Measuring Device List
            (1) Operators
            (2) Calibration Requirements
                (a) Schedule
                (b) Procedures
            (3) Calibration Inspection Records
                (a) Corrective Action Reports
        b. Design Reviews
        c. Nonconformance Reports
            (1) Corrective Action Reports
    2. Cement and Pozzolan Unit
        a. Measuring Device List
            (1) Operators
            (2) Calibration Requirements
                (a) Schedule
                (b) Procedures
            (3) Calibration Inspection Records
                (a) Corrective Action Reports
        b. Design Reviews
        c. Nonconformance Reports
            (1) Corrective Action Reports
    3. Chemistry Unit
        a. Measuring Device List
            (1) Operators
            (2) Calibration Requirements
                (a) Schedule
                (b) Procedures
            (3) Calibration Inspection Records
                (a) Corrective Action Reports
        b. Design Reviews
        c. Nonconformance Reports
            (1) Corrective Action Reports
    4. Petrography Unit
        a. Measuring Device List
            (1) Operators

(2) Calibration Requirements
    (a) Schedule
    (b) Procedures
(3) Calibration Inspection Records
    (a) Corrective Action Reports

b. Design Reviews

c. Nonconformance Reports
(1) Corrective Action Reports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